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EXAMINER

BALLARD, KIMBERLY A

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1649

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/506,665	Applicant(s) SOLOMON, BEKA	
	Examiner Kimberly A. Ballard	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 23-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 23-26, 28, 30-37, 39 and 41 is/are rejected.
- 7) ☒ Claim(s) 27, 29, 38 and 40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

Status of Application, Amendments and/or Claims

Claim 15 has been amended and new claims 23-41 have been added as requested in the amendment filed March 19, 2007. Following the amendment, claims **1-15** and **23-41** are pending and under examination in the current office action.

Withdrawn Objections and/or Claim Rejections

Specification

The objections to the disclosure, regarding a supposed typographical error in the sequence listing and also sequences within the specification requiring sequence identifiers, are withdrawn in view of Applicant's amendments to the specification and sequence listing. The correction to Figure 1 is also noted and entered of record.

The rejection of claims 11 and 14 as being unpatentable on the ground of provisional nonstatutory obviousness-type double patenting over claims 10 and 11 of copending Application No. 11/475,247 ('247 application) is rendered moot in view of the fact that the '247 application has been abandoned.

Applicant's arguments, see pages 18-19 of the response filed March 19, 2007, with respect to claim 1 have been fully considered and are persuasive. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by US Patent 5,721,130 to Seubert et al. has been withdrawn.

Maintained Claim Rejections

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 1-3, 5-10 and 15 under nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 6, 10, 16-17 and 21-24 of copending Application No. 10/481,642 ('642 application) is maintained for reasons of record and is further applied to new claims 23-25, 28, 30-34 and 41.

In the response filed March 19, 2007, Applicant argues that the claims of the '642 application are directed to an antigenic product carrying an antigenic peptides that comprises epitopes of amyloid β , but not the β -secretase cleavage site (e.g., the intact β -secretase cleavage site is not present in amyloid β). Moreover, Applicant argues, A β PP (APP) as the precursor protein is not a deposit-forming polypeptide as it itself

does not form a deposit. As such, Applicant asserts that the instant claims directed to an antigenic product which induces an immune response against the β -secretase cleavage site of A β PP are not obvious over claims to an antigenic product comprising an epitope that only appears in amyloid β , a product of β -secretase cleavage of A β PP.

Applicant's arguments have been fully considered but they are not persuasive. The claims of copending application '642 are directed to an antigenic product comprising an antigenic peptide "that comprises an epitope of a deposit-forming polypeptide involved in plaque-forming disease or disorder". As Applicant duly notes, the entire A β PP molecule comprises the amyloid β polypeptide, and accordingly A β PP would comprise an epitope of a deposit-forming polypeptide involved in plaque-forming disease or disorder (i.e., amyloid β). This is evidenced by instant claim 5, for example, which recites that the A β PP epitope spanning the β -secretase cleavage site of A β PP comprises SEQ ID NO: 5, which is the sequence VKMDAEFRH. This epitope *comprises* an epitope known to be associated with the deposit-forming amyloid β polypeptide, namely EFRH. The skilled artisan would recognize that administration of an immunizing composition comprising VKMDAEFRH would produce a polyclonal antibody response comprising antibodies directed not only to the β -secretase cleavage site as instantly claimed, but also to the highly antigenic portion of amyloid β , particularly the EFRH epitope. Additionally, because the claims of the '642 recite similar comprising language, such as claim 6 which recites that the polypeptide comprises the amino acid sequence EFRH, such is not limiting to those sole amino acid residues and would reasonably be encompassed by, and therefore render obvious, a larger antigenic

peptide comprising, for example, VKMDAEFRH (instant SEQ ID NO: 5). Therefore, the provisional obviousness-type double patenting rejection of instant claims 1-3, 5-10, 15, 23-25, 28, 30-34 and 41 is maintained and held in abeyance until all other rejections are resolved.

The rejection of claims 11, 12 and 14 under the doctrine of provisional nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3 and 10 of copending Application No. 11/073,526 ('526 application) is maintained for reasons of record and is similarly applied to new claims 35, 36 and 39.

In the response filed March 19, 2007, Applicant argues, as in the above rejection over application 10/481,642, that an epitope of amyloid b (as recited in the '526 application) does not contain the β -secretase cleavage site of A β PP and therefore would not induce an immune response against the β -secretase cleavage site of A β PP as required by the instant claims.

Applicant's arguments have been fully considered but they are not persuasive. Similar to the situation discussed above, the claims of the '526 application are directed to an antigenic virus particle displaying a polypeptide, wherein said polypeptide *comprises* at least one epitope of amyloid β . Thus, the polypeptide is not limited to epitopes only contained only within amyloid β . Also, as noted above, the A β PP molecule comprises the amyloid b polypeptide, such that the species of antigenic peptide recited in claim 10 of the '526 application, namely an epitope comprising EFRH, would anticipate the genus of antigenic molecule instantly claimed which reasonably

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comprises such an amyloid β epitope. Accordingly, the provisional obviousness-type double patenting rejection of instant claims 11, 12, 14, 35, 36 and 39 is maintained and held in abeyance until all other rejections are resolved.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 1 and 15 under 35 U.S.C. 102(e) as being anticipated by WO 01/53457 A2 by Srivastava (priority to January 21, 2000), as evidenced by Vassar et al. (*Science*, 1999; 286: 735-741), is maintained for reasons of record.

In the response filed March 19, 2007, Applicant argues that while Srivastava “discloses a mutation at codon 671 (P2) or codon 672 (P1) of A β PP (APP), there is no disclosure that the antigenic peptide induces an immune response against the β -secretase cleavage site as recited in instant claim 1.” Applicants thus assert that there can be antigenic peptides of a mutant A β PP which may contain a mutation at codon 670 or 671, but do not contain an epitope that spans the β -secretase cleavage site.

Applicant's arguments have been fully considered but they are not persuasive. In response to applicant's argument that the Srivastava reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., an A β PP spanning the β -secretase cleavage site) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Instant claim 1, for example, is drawn to an immunizing composition comprising an antigenic product which induces an immune response against the β -secretase cleavage site of amyloid precursor protein (APP). As stated previously, Srivastava discloses antigenic peptides comprising amino acid sequences derived from APP, or fragments thereof (see p. 9, lines 28-30). For example, Srivastava teaches that peptide fragments of a mutant APP comprising a mutation at codon 670 or 671 may be used as an antigen (p. 9, lines 31-33). Such a peptide fragment would reasonably also comprise the β -secretase cleavage site of APP, which is located between residues 671 and 672 of APP, and therefore administration of Srivastava's antigenic peptide would inherently be expected to lead to the induction of an immune response against the β -secretase cleavage site of APP. Further, the immune response would inherently result in the blockade of β -secretase cleavage of APP, and would thereby inhibit the formation of amyloid β , thus meeting the recited limitations of instant claim 15. This is evidenced by the fact that the antigenic compositions disclosed by Srivastava are taught to be useful as vaccines to protect against and/or treat neurodegenerative diseases and disorders, such as Alzheimer's disease (see

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paragraph spanning pp. 7-8), which is, of course, a disease characterized by abnormal amyloid β formation and deposition. Accordingly, the rejection of instant claims 1 and 15 is maintained.

The rejection of claims 1-11 and 13-15 under 35 U.S.C. 102(b) as being anticipated by WO 00/72880 A2 by Schenk et al. (published December 7, 2000) is maintained for reasons of record and is further applied to new claims 23-26, 28, 30-35, 37, 39 and 41.

In the response filed March 19, 2007, Applicant asserts that the addition of the limitation "human" subject to claim 15 obviates the instant rejection referring to PDAPP mice as "a subject in need thereof". Applicant further argues that the APP polypeptide disclosed by Schenk containing residues 592-695 is 104 residues long and would therefore contain many epitopes besides an epitope spanning the β -secretase cleavage site. Moreover, Applicant argues that there is no disclosure in Schenk of the specific epitopes spanning the β -secretase cleavage site in A β PP and there is no certainty of inducing an immune response against this site.

Applicant's arguments have been fully considered but they are not persuasive. The amino acid length of the immunogenic pBx6 polypeptide taught by Schenk is irrelevant because the polypeptide still *comprises* an A β PP epitope spanning the β -secretase cleavage site, which would thus comprise the instantly claimed peptides of SEQ ID NO: 5 and residues 1 to 8 of SEQ ID NO: 1. Moreover, Schenk discloses shorter antigenic peptide fragments that comprise the β -secretase cleavage site in

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Figures 19 and 20. Examples of these peptides include VKMDAEFRHD and ISEVKMDAE, which comprise instant SEQ ID NO: 5 (VKMDAEFRH) and residues 1 to 8 of SEQ ID NO: 1 (ISEVKMDA), respectively. Regardless of whether the longer 104 amino acid pBx6 polypeptide or the shorter A β PP peptide fragments noted above are administered as immunizing agents, the immunization would inherently be expected to produce at least some antibodies directed against the β -secretase cleavage site of A β PP and thus meet the instantly recited limitations. Additionally, while it was noted that the pBx6 polypeptide was specifically disclosed as being administered to PDAPP mice, the overall disclosure by Schenk is directed to methods of treating or preventing a disease associated with amyloid deposits of A β in the brain of a patient, such as Alzheimer's disease, Down's syndrome and cognitive impairment (see p. 2, lines 28-30), wherein the patient is usually a human (see p. 37, lines 1-3), and would thus anticipate amended claim 15 as well as new claim 41. Accordingly,

Further, Schenk teaches that immunogenic peptides, such as fragments of A β or APP as above, can be presented by a virus as part of an immunogenic composition (see p. 16, lines 16-17), thus meeting a recited limitation of instant claims 11 and 35. Schenk also teaches that immunogenic peptides can be expressed as fusion proteins with a carrier peptide, such as a T helper cell epitope, which can serve to induce a helper T-cell response against the carrier peptide. The induced helper T-cells in turn induce a B-cell (i.e. antibody) response against the immunogenic peptide (see p. 29, lines 20-28). Schenk discloses that the fusion proteins comprising the immunogenic peptide can then be linked to a core molecule, such as lysine, to form a multimer of

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fusion proteins. The multimer is represented by the formula 2^x , in which x is an integer from 1-5, preferably x is 1, 2 or 3 (see p. 30, lines 13-22). For example, when x is 3, such a multimer has eight fusion proteins linked to a core molecule, thus addressing recited limitations of instant claims 2-3 and 24-25 regarding the number of function groups. Schenk teaches an example of the MAP4 (Multiple Antigen Peptide) configuration, in which 4 identical peptides have been produced on the branched lysine-containing core structure (see paragraph spanning pp. 30-31). Schenk teaches that such multiplicity greatly enhances the responses of B cells (see p. 30, line 29). Accordingly, these teachings would anticipate limitations recited in instant claims 6 and 30 (overlapping APP epitopes), 7 and 31 (wherein the overlapping epitopes are identical), and 8 and 32 (core molecule is lysine). The T helper cell epitope, which would be part of the fusion peptide comprising the immunogenic peptide, would thus meet a limitation of instant claims 9 and 33, which recite that the composition further comprises a molecule having adjuvant properties joined to said dendritic polymer. Further, Schenk discloses that pharmaceutical compositions comprising the immunogenic peptides can be encapsulated in liposomes or micro particles for enhanced adjuvant effect (see p. 41, lines 29-33), thus addressing a recited limitation of instant claims 10 and 34. Accordingly, the rejection of claims 1-11, 13-15, 23-26, 28, 30-35, 37, 39 and 41 is maintained.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection of claims 11 and 12 under 35 U.S.C. 103(a) as being unpatentable over WO 00/72880 A2 by Schenk et al. (published December 7, 2000), in view of Frenkel et al. (*Proc Natl Acad Sci USA*, 2000; 97(21): 11455-11459) is maintained for reasons of record and is further applied to new claim 36.

The claims are drawn to an immunizing composition comprising a viral display vehicle displaying on its surface an A β PP epitope spanning the β -secretase cleavage site of A β PP (claim 11), wherein the viral display vehicle is a filamentous bacteriophage (claims 12 and 36).

In the response filed March 19, 2007, Applicant argues that Frenkel only teaches β -amyloid epitopes and does not provide any suggestion or motivation to induce an immune response against the β -secretase cleavage site or to use an epitope spanning

the β -secretase cleavage site to raise such an immune response. Applicant asserts that there is no teaching, suggestion or motivation in either Schenk or Frenkel that would lead one of ordinary skill in the art to arrive at the presently claimed invention.

Applicant's arguments have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As discussed above, the Schenk reference discloses antigenic fragments comprising the β -secretase cleavage site of AbPP displayed on viruses, but does not specifically disclose that the viral display vehicle is a filamentous bacteriophage. The Frenkel reference is thus provided to teach filamentous bacteriophages useful for immunization procedures. The fact that only β -amyloid epitopes were utilized by Frenkel is thus irrelevant, because it is general teaching of increased antigenicity of epitopes displayed by a filamentous bacteriophage that the skilled artisan would recognize as being useful for the production of immunizing compositions. For example, Frenkel teaches that because of the high antigenicity of the phage, no adjuvant is required to obtain high affinity antibodies after a short immunization period of 3 weeks (see Abstract). Additionally, Frenkel notes that the availability of such antibodies opens up possibilities for the development of an efficient and long-lasting vaccination for the treatment of Alzheimer's disease (see Abstract), which is also a disclosed goal of Schenk (noted above). Thus,

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the combined references render instant claims 11, 12 and 36 obvious to one of ordinary skill in the art at the time the invention was made.

New Claim Rejections, Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 recites the limitation "said *at least one* A β PP epitope" in lines 3-4. It is noted that claim 35 depends from claim 1. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

Applicant is advised that should claims 11-14 be found allowable, claims 35-37 and 39 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

Claims 1-15, 23-26, 28, 30-37, 39 and 41 are rejected. Claims 27, 29, 38 and 40 are objected to as being dependent upon a rejected base claim, but would otherwise be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Ballard whose telephone number is 571-272-4479. The examiner can normally be reached on Monday-Friday 9AM - 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kimberly Ballard, Ph.D.
November 16, 2006

Elizabeth C. Kemmerer

ELIZABETH C. KEMMERER, Ph.D.
PRIMARY EXAMINER